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10/692,996	10/24/2003	Jay Prabhakar Gore	3220-73780	9342

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EXAMINER	
GAKH, YELENA G	

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1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,996	GORE ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-13 and 16-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-13 and 16-69* is/are rejected.

7)☒ Claim(s) *8,16,28,35,36,57 and 58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 03/10/08 is acknowledged. Claims 6-7 and 14-15 are cancelled. Claims 1-5, 8-13 and 16-69 are pending in the application.

Response to Amendment

2. Amendment introduces a new definition in the pending claims, "an optical sensor" (*aka* "optical detector") and "optical detection". By definition, "an optical detector: a transducer that generates an output signal when irradiated with optical energy (188). Aug 23, 1996: (http://www.its.bldrdoc.gov/fs-1037/dir-025/_3711.htm. This definition includes generating an electrical signal. If the Applicants mean something else by the term "optical sensor", it is not clearly defined in the specification, and therefore an issue of new matter introduced into the originally filed disclosure can be raised. Since no specific definition for "optical sensor (detector)" is provided in the instant specification, the examiner interprets the term according to its conventional usage.

3. Objection to the specification and claims, and rejections of the pending claims under 35 U.S.C. 112, first and second paragraphs, are modified in view of the amendment. Rejection over the prior art is maintained.

Specification

4. The disclosure is objected to because of the following informalities:

A. On page 2 the full name for EDTA should be written as "Ethylenediamine tetraacetic acid" (if the word "ethylenediamine" cannot be written in one line, the word can be divided as "ethylene-diamine"). "Diamine" is misspelled in the claim.

On page 3 the full name for IR is "infrared", rather than "infra-red".

On page 5 the full name for PTFE should be written as "poly(tetrafluoroethylene)".

On page 6 the full name for DNA should be written as "deoxyribonucleic acid".

Appropriate correction is required.

B. Amended equations (2)-(4) define the mean centered integrated absorbance as IA, while in equation (1) it is defined as IAR, which makes the terms inconsistent.

C. Amended equations (2) and (3) became the same equation. Appropriate correction is required.

D. If the Applicants intend to use different measurement units for IR absorption ranges and bands, i.e. wavenumbers (cm^{-1}) and wavelengths (μm or microns), the examiner respectfully requests the Applicants to provide both values in each case, since otherwise a practitioner in the art should recalculate the values provided in one unit into another to compare the ranges, which is cumbersome and inconvenient.

E. In paragraph [00155] the sentence "This a second modulation technique is particularly useful ... " should be corrected.

Double Patenting

5. A. Applicant is advised that should claim 2 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being an exact duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

B. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 8-13 and 16-69 of the instant application are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,288,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite essentially the same subject matter for the method of detecting an organic compound, in particular glucose in the instant application and fat in the patent, using IR spectroscopy with converting optical signals from several absorption ranges into electrical signals with the following processing of the signals using a multivariant calibration algorithm.

Claim Objections

6. A. Amended claims 8, 16 and 58 are objected to for the following informalities: they recite the measurement unit for IR absorption band (microns), which is inconsistent with the measurement unit recited in other claims (cm^{-1}). If the Applicants intend to use both measurement units for IR absorption bands, i.e. wavenumbers (cm^{-1}) and wavelengths (μm or microns), amended claims 8, 16 and 58 should recite both units, rather than just one of them.

B. Amended claims 28 and 57 recite the term "thickness" of an absorbance band, which is not an accepted term in optical spectroscopy. The conventional term is "width". Appropriate correction is required.

C. Amended claims 35 and 36 misspell the word "said". Correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 19-22 recite that "the mean-centered concentration of glucose in said

biological fluid being calculated with the equation: ...". The specification discloses: "C_g is the mean centered concentration of glucose in solution measured using methods other than IR absorption" (see paragraphs [00158], [00164], [00165] and [00170]). Moreover, the specification discloses that the equations (1)-(4) utilize the known C_g values in order to obtain calibration coefficients P_1-P_n (n=1-9) for further application of the calibration algorithm in determining an unknown amount of glucose. This discrepancy raises reasonable doubts as to possession of the invention recited in claims 19-22 at the time of filing the application.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 18-22 and 28-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The relation of the subject matter of claim 2 to that of claim 1 is not quite apparent. Is claim 2 supposed to recite just that "The method of claim 1, wherein the organic compound is glucose", or it means something else? If it is the first case, the examiner respectfully requests the Applicants to re-write the claim in this simple and clear form.

Claim 18 recites the limitation "electromagnetic radiation absorbed by glucose contained within said biological fluid", which does snot have an antecedent basis, since no glucose was recited in the parent claim. This uncertainty renders claim 18 and all dependent claims unclear and indefinite.

Claim 19 recites the equation in which the mean-centered integrated absorbance ratio is defined as IAR, while all other analogous claims 20-22 define it as IA.

Claim 20 appears to recite the incorrect equation, as was indicated in the previous Office action. If the equation will be amended in correspondence with the amended specification, claims 20 and 21 will recite the same equation. The examiner respectfully suggests the Applicants to resolve the problem by careful reconsideration of equations (3) and (4).

The subject matter of claims 19-22 contradicts a respective disclosure in the specification. According to the specification, C_g is a known mean-centered concentration of

glucose measured by the methods other than IR, and is used in the equations for determining calibration constants P_i.

Amended claims 28 and 57 are confusing. First, it is not clear, what the expression "said incident signal comprises at least two glucose absorbance bands each having a thickness of at least 140 nm", means. The examiner does not quite understand the expression. If this is the incident signal emitted by the source of radiation and passing through the sample, then how can it comprise "at least two glucose absorbance bands each having a thickness of at least 140 nm"? An incident signal always has a specific frequency range and intensity (power). It does not comprise any "absorbance bands". The wavelength range for the incident radiation can comprise the spectral range for the absorbance of the specific compound, e.g. glucose, but it is totally unclear, as to how it can comprise the absorbance band of a specific "thickness". Also, what is a "thickness" for the spectral band? The examiner has never seen this term before. Is this the width of the spectral line? The recitation of claims 28 and 57 renders them unclear and indefinite, which renders all dependent claims unclear and indefinite. The examiner interprets the claims as reciting the wavelength range of the incident radiation comprising the absorption frequencies of glucose, which inherently include the width of the corresponding glucose absorption signals.

Further, the examiner does not quite understand, what the expression, "resulting from filtering of said incident infrared (infrared what?) upon passing through said sample", means. The examiner was not able to interpret this expression in a sensible manner, and therefore is forced to disregard it at this time.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 1-5, 8-9, 11-13 and 16-27** are rejected under 35 U.S.C. 102(e) as being anticipated by Lillenfeld-Toal (US 6,484,044) as evidenced by Peralta et al. (J. Phys. E. Sci., 1988).

Lillenfeld-Toal teaches a method of measuring an amount of an organic substance (glucose) contained within a biological sample, the compound having an infrared absorption spectrum, which includes a set of wavelength regions (see Figure 3), the method comprising detecting a number of selected wavelength bands from the spectrum less than the total number of the wavebands of the compound: for example detecting at least three different wavelengths (col. 4, lines 1-2) of selected wavenumbers 1151, 1105, 1080, 1036 and 992 cm^{-1} (col. 4, line 15) (corresponding detecting in the regions recited in claims 6-8 and 14-16); generating an electrical signal in photoacoustic sensor (in piezoelectric transducer 6, col. 3, lines 44-45) in response to detecting the intensity of the bands at these wavenumbers; and processing said electrical signal with a quantification algorithm, e.g. "by a least square calculation referring to reference spectra such as shown in FIGS. 2 or 3 for known glucose concentrations. The calculated concentration is displayed on display 9. Alternatively, the glucose concentration could also be calculated from an average of concentrations obtained from the absorptions at each wavelength relative to reference absorption for a reference glucose concentration determined beforehand" (col. 4, lines 26-34) (claims 3-5). Equations recited in claims 19-22 are conventional equations for partial least square analysis with the number of contributions defined by the number of input wavelengths.

Peralta et al. describe photoacoustic detector disclosed by Lillenfeld-Toal as an optical detector, i.e. "photoacoustic optical power meter using piezoelectric detection" (Title).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfeld-Toal as evidenced by Peralta et al..

Regarding claim 10, while Lillenfeld-Toal does not specifically teach filtering the biological sample, it is a conventional procedure for invasive vs. non-invasive detection of glucose. Lillenfeld-Toal discloses the method for detecting glucose both in tissue (non-invasive)

and in blood (invasive) (see Abstract), and therefore it would have been obvious for any person of ordinary skill in the art to filtrate the biological sample before IR spectroscopic measurements.

13. **Claims 28-51 and 56-69** are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Heise et al. (Appl. Spectr., 1994) (Heise), Bhandare et al. (Appl. Spectr., 1994) (Bhandare), Budinova et al. (Appl. Spectr., 1997) (Budinova), or Vonach et al. (Appl. Spectr., 1998) (Vonach) in view of Purdy et al. (US 5,460,177).

All references disclose a method of measuring a glucose level within a biological sample using mid-infrared spectroscopy by measuring a set of wavelength regions, in which glucose absorbs in mid-IR range: 1200-950 cm^{-1} (see e.g. Heise, page 88, left column) by obtaining a sample of a biological fluid, passing an incident signal of indicated wavelength through the sample, detecting a post-absorbance signals and calculating glucose concentration from said post-absorbance signal. All references disclose detecting glucose at specific wavelengths: "for glucose, the best predicting results were achieved within the rather narrow spectral range of 1200 to 950 cm^{-1}, where the most intensive absorption bands of aqueous glucose exist" (Heise, page 88, left column); Budínova discloses the following wave-numbers for glucose, which slightly differ from the ones recited in the claims: 1035, 1078, 1104 and 1148 cm^{-1} with the full range of 1185-950 cm^{-1}; Vonach indicates that "the spectral change [upon adding glucose] is in accordance with the glucose absorption with its maxima at 1038 and 1080 cm^{-1}" (page 821, left column).

Heise, Bhandare, Cadet, Budínova or Vonach do not specifically disclose modulating the incident signal upon irradiating the sample with mid-IR radiation. However, overheating the biological sample with intensive NIR or mid-IR radiation is a problem in analysis of component of biological sample, as discussed by Purdy.

Purdy indicates: "[c]ontinuous-spectrum noninvasive techniques make use of radiation in the near-infrared portion of the spectrum. However, in this portion of the spectrum, the absorption of radiation by water is very high. In addition, the concentrations of the analyte of interest in the bloodstream is typically low. As a result, the contribution of the analyte of interest to the signal intensity is only a relatively small change in the total signal intensity obtained by this technique. It has been found that detector noise is of the same order of magnitude as the change in intensity signal resulting from variations in analyte concentration. The variations in

signal intensity as a result of variations in concentration of the analyte of interest are so small that, at intensities that have been used in the past, the detector's sensitivity may not be high enough to obtain sufficiently accurate readings. A possible solution to this problem would be to increase the intensity of the radiation incident on the body part of the subject. However, an increase in the intensity of incident radiation increases the amount of energy absorbed by the body part. Increases in the energy absorbed by the body part result in greater heating of the body part the amount of heat produced. Excessive heating can cause discomfort and even burns to the subject, which obviously would be undesirable. It is accordingly an object of this invention to provide a method for the continuous spectrum non-invasive spectroscopic detection of analytes in the bloodstream of living animals with increased signal-to-noise ratio" (col. 1, lines 64-67 and col. 2, lines 1-25).

Purdy provides a solution to the problem by using a chopper for periodically interrupting radiation emitted from the bulb, i.e. modulating intensity of the incident signal: "A method for non-invasive detection of the concentration of an analyte in the blood of a living animal includes the steps of irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum; detecting the intensity of radiation emitted from the body part at a plurality of discrete wavelength ranges within the continuous spectrum; and using the detected intensity to calculate the concentration of the blood analyte" (col. 2, lines 31-39)

It would have been obvious for any person of ordinary skill it the art to modulate intensity of the incident signal as taught by Purdy in any of Heise, Bhandare, Cadet, Budínova or Vonach's methods for the reasons analogous to the ones indicated by Purdy, i.e. in order to prevent overheating of the sensitive biological sample, because the analysis is performed by using radiation in thermal range (mid-IR frequencies).

While none of the specific references teaches filtrating the biological sample before performing measurements, it is a conventional step in most analytical spectroscopic studies of biological samples, as admitted by the Applicants (see page 24, paragraph [100]) and therefore it would have been obvious for any person of ordinary skill in the art to filtrate biological samples using ultrafiltration techniques well known in the art.

Since the measurement path is defined by penetration of the mid-IR incident radiation and therefore defined the output data, it would have been obvious for any person of ordinary skill

in the art to optimize the penetration depth (measurement path) in order to obtain the most accurate results by comparing with the reference data.

14. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Heise, Bhandare, Budinova, or Vonach in view of Purdy, as applied to claims 28-51 and 56-69, and further in view of Rule et al. (US 2003/0040683 A1) (Rule).

Heise, Bhandare, Budinova, or Vonach in view of Purdy do not specifically disclose the second modulation technique, which comprises e.g. modulating of laser emitted signal with a specific frequency, such as in the range of 0.1 Hz-10 Hz, specifically 3 Hz.

Rule discloses "site selection for determining analyte concentration in living tissue" (Title) with the analyte being glucose and the analytical method - IR spectroscopy. In particular, Rule teaches: "[0152] The radiation emitted from the source 220 is in one embodiment modulated at a frequency between about one-half hertz and about one hundred hertz, in another embodiment between about 2.5 hertz and about 7.5 hertz, in still another embodiment at about 50 hertz, and in yet another embodiment at about 5 hertz. With a modulated radiation source, ambient light sources, such as a flickering fluorescent lamp, can be more easily identified and rejected when analyzing the radiation incident on the detector 250".

It would have been obvious for a person of ordinary skill in the art to further modify the method of Heise/Bhandare/Budinova/Vonach-Purdy by applying the second modulation technique, such as the one disclosed by Rule, i.e. modulating radiation emitted by the IR source with the frequency within 0.1Hz-10 Hz range, because of the same reasons as indicated by Rule, e.g. in order to identify interfering radiation sources and correct for possible errors. It would have been obvious for a person of ordinary skill in the art to optimize the frequency of modulation within this range, and choose the frequency of 3 Hz for specific IR sources.

It would have been obvious for a person of ordinary skill in the art to substitute IR chopper, which blocks IR radiation, with the IR absorbing material, because it gives the same effect of preventing IR radiation from reaching the sample, and thus prevents overheating the sample.

Response to Arguments

15. Applicant's arguments filed 03/10/08 have been fully considered but they are not persuasive. However, the examiner appreciates the Applicants' work in amending the claims, which resulted in resolving many 112, first and second paragraphs, issues.

The examiner believes that remaining and new objections to the specification and claims, and rejections of the claims under 35 U.S.C. 112, first and second paragraphs, are self-explanatory from the Office action.

The examiner respectfully disagrees with the Applicants' arguments regarding rejection of the pending claims over the prior, because Lillenfeld-Toal's photoacoustic detector is an optical detector, as clearly demonstrated in the present Office action.

The Applicants' arguments related to claims 28 and 57 are not apparent to the examiner. The subject matter of the claims is also not clear. The examiner respectfully requests the Applicants to elaborate their position regarding these claims in response to the present Office action. If the Applicants indicate that the prior art does not disclose a specific bandwidth for glucose absorption lines, these spectral parameters are inherent to absorption spectra.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

05/14/2008